

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated August 17, 2004 are respectfully requested.

Applicants thank the Examiner for an indication that claims 10, 19, 23, and 34-36 are allowable.

I. Amendments

Claim 15 stands canceled.

Claim 17 is amended to recite features of claim 15.

No new subject matter has been added by way of these amendments.

II. Rejection under 35 C.F.R. §102

Claim 15 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Vlasov, et al. (*Biopolim. Kletka*, 4(3):113-168 (1988)).

Claim 15 stands canceled, rendering the rejection moot. Withdrawal of the rejection is respectfully requested.

III. Rejections under 35 C.F.R. §103

Claims 15 and 17 were rejected under 35 U.S.C. §103 as allegedly obvious over Vlasov et al. further in view of Hoon et al. (U.S. Patent No. 6,472,375). This rejection is respectfully traversed.

A. The Present Invention

The present invention, as embodied by amended claim 17, relates to a method for preparing a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope for gene transfer. The method comprises the steps of (i) mixing a virus with the exogenous gene, (ii) freezing and thawing the mixture two or more times; and (iii) inactivating the virus.

**B. The Prior Art**

VLASOV ET AL. relates to a method for encapsulation of DNA into reconstituted Sendai virus envelopes (RSVE). Cells of Krebs-2 acites tumor were incubated with RSVE or virus in the same medium. After incubation, unbound RSVE was washed from the cells. The cells were precipitated by centrifugation. Cell nuclei were isolated from the cells with a hypotonic solution and precipitated by centrifugation. The DNA was encapsulated in RSVE with five freezing-thawing cycles.

HOON ET AL. The Hoon *et al.* patent was published on October 29, 2002 and names as co-inventors Dave S.B. Hoon and Yasufumi Kaneda. Mr. Kaneda is the sole inventor of the instant application. The present application was filed February 21, 2002 and claims priority to PCT application no. PCT/JP01/00782, filed February 2, 2001, which claims priority to Japanese application no. 25596, filed February 2, 2000.

Under M.P.E.P. § 715.01(a) and § 716.10, when subject matter, disclosed but not claimed in a patent or application publication filed jointly by S and another, is claimed in a later application filed by S, he or she may overcome the rejection by filing an unequivocal declaration that he/she conceived or invented the subject matter disclosed in the patent or application publication and relied upon in the rejection. Disclaimer by the other patentee or applicant of the application publication should not be required.

Enclosed herewith is a declaration by Mr. Yasufumi Kaneda showing that he conceived or invented the subject matter disclosed in Hoon *et al.* Specifically, and as stated in point 3 of the Declaration, the immunization protocol relied on in the present rejection was conceived of by the Mr. Kaneda and thus represents the Applicant's own work. Accordingly, the Hoon *et al.* patent is not available as prior art under 35 U.S.C. §103.

### C. Analysis

According to the MPEP § 2143, one of the three basic criteria to establish a *prima facie* case of obviousness is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

Claim 15 stands canceled. As noted above, the Hoon *et al.* patent is not available as prior art. The rejection is discussed with reference to the remaining Vlasov *et al.* article.

As described above, the method of amended claim 17 includes the step of inactivating the virus. Vlasov *et al.* fail to teach this step of inactivating the virus.

Because the cited Vlasov *et al.* reference fails to teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

### IV. Conclusion

In view of the foregoing, Applicant submits that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,



Jacqueline F. Mahoney  
Registration No. 48,390

Date: Nov. 17, 2004

### Correspondence Address:

Customer No. 22918  
Phone: (650) 838-4300